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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 09/047,652  | 03/25/1998  | VASSILIOS PAPADOPOULOS | 009/064/SAP         | 3470             |
| 21186   | 7590        | 12/27/2006             | EXAMINER            |                  |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.<br>P.O. BOX 2938<br>MINNEAPOLIS, MN 55402 |             |                        | DAVIS, MINH TAM B   |                  |
|   |             | ART UNIT               |                     | PAPER NUMBER     |
|   |             |                        |                     | 1642             |
| SHORTENED STATUTORY PERIOD OF RESPONSE  | MAIL DATE   | DELIVERY MODE          |                     |                  |
| 3 MONTHS  | 12/27/2006  | PAPER                  |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/047,652             | PAPADOPOULOS ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MINH-TAM DAVIS         | 1642                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 October 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 53-55,58-60,63,64,66-68,70,72-74, 78,79,81,82 is/are pending in the application.
- 4a) Of the above claim(s) 58-60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 53-55,63,64,66-68,70,72-74,78,79,81 and 82 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/12/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Accordingly, claims 53-55, 63-64, 66-68, 70, 72-74, 78-79, 81-82 are examined in the instant application.**

***Claim Rejections - 35 USC § 101, Utility***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 53-55, 63-64, 66-68, 70, 72-74, 78-79, 81-82 remain rejected under 35 USC 101, for lack of support by either a specific or well established utility, for reasons already of record in paper of 07/12/06.

The response asserts that variants PBR gene disclosed in the instant specification has been detected in Jurkat cells and human genomic DNA, as taught by Costa et al, 2006, and Kurumaji et al, 2002. The response asserts that overexpression of PBR is associated with an aggressive phenotype in certain tumors, as taught by Morgan et al, 2004, Maaser et al, 2002, and Han et al, 2003, and concludes that thus detection of PBRs in these tumor would be useful for detecting the aggressiveness of cancer. Further, a Declaration by Dr. Papadopoulos is submitted. In the Declaration, variant codon 147 PBR mRNA is found in colon and breast tumor biopsies.

Art Unit: 1642

The recitation of Costa et al, 2006, and Kurumaji et al, 2002, Morgan et al, 2004, Maaser et al, 2002, and Han et al, 2003 and the submission of the Declaration by Dr. Papadopoulos are acknowledged and entered.

The response has been considered but is not found to be persuasive for the following reasons:

The claimed nucleic acid encodes a PBR protein having both two mutations, one at position 147 and one at position 162. The Declaration however shows that only one mutation, at position 147, exists in colon and breast cancer biopsies. Further, the submitted abstract of Kurumaji et al, 2002, does not teach that the two mutations in BPR gene in the Japanese sample are the same as the claimed mutation at positions 147 and 162, nor any association of these mutations with disease. Moreover, the Jurkat cells taught by Costa et al, 2006, are cells in tissue culture only, and not cancer tissue.

One cannot however determine that the single mutation at position 162, or the encoded residues 27-169 of SEQ ID N:3, having mutation at both positions 147 and 162 exists in human cancer tissue. The mutation at position 162 is found only in cancer cells in tissue culture, and thus one cannot predict that said mutation also exist in cancer tissue, due to the well known cell culture artifacts, in view of the teaching of Drexler et al, Embleton et al, Hsu et al, Tian et al, Van Dyke et al, Zaslav et al, and Kunkel et al, all of record, and in view that each mutation is an independent, unpredictable event.

Moreover, although overexpression of PBR is associated with an aggressive phenotype in certain tumors, whether these tumors have the claimed mutations at position 162, or at both positions 147 and 162 is not predictable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

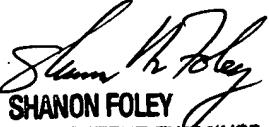
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS  
December 18, 2006



SHANON FOLEY  
SUPERVISORY PATENT EXAMINER  
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